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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,701	04/24/2000	Hitoo Nishino	0010-1106-0	7992

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/556,701

Applicant(s)

Nishino

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 27, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

The request for filing under 1.53 (d) and the preliminary amendment dated 2-27-02 are acknowledged.

Claims included in the prosecution are 1-12.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 4 and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The distinction between ‘composition’ in claim 1 and ‘pharmaceutical composition’ in claim 2 is unclear. Whatever way a pharmaceutical is administered, since the compound is a pharmaceutical, the composition would be a pharmaceutical composition.

Claim 1 is already drawn to bran edema; claims 4 and 9 thus, are not further limiting claim 1.

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It is unclear what applicant intends to convey by 'foodstuff' in claim 12. Similar is the case with 'additive for incorporating melatonin in food'. What is this additive?

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,075,045.

Although the conflicting claims are not identical, they are not patentably distinct from each other because instant treatment of brain edema is deemed to result in the treatment of infarction and subsequent paralysis claimed in the claims of said patent.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/20555 of record.

WO discloses a method of treatment or prevention of ischemic brain injury by administering melatonin (note the abstract, page 8, lines 10-30, page 9, lines 22-34, page 11, lines 14-16, Examples and claims). Since ischemia is the causative factor of brain edema, the prevention and the treatment thus, are implicit in WO's teachings.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO cited above.

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As discussed above, WO discloses a method of treatment or prevention of ischemic brain injury by administering melatonin (note the abstract, page 8, lines 10-30, page 9, lines 22-34, page 11, lines 14-16, Examples and claims). Since ischemia is the causative factor of brain edema, it would have been obvious to one of ordinary skill in the art that a composition which is able to prevent ischemia would be preventing the edema also. Although WO does not specifically state the composition is a food composition, it teaches the administration of the composition orally using additives and therefore, addition to food for oral consumption is deemed to be within the skill of the art.

9. Claims 1, 3-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuzzocrea (J. Pineal Res., 24, pp 106-116, 1997) in view of Guerrero (J. Pineal Res. 24, 24-31, 1997), optionally further in view of WO 98/21947.

Cuzzocrea discloses the protective effect of melatonin in an experimentally induced inflammation (and edema) model. Cuzzocrea further discloses the relationship between melatonin's inhibitory effect on nitric oxide production and its peroxynitrite scavenging activity. According to Cuzzocrea, melatonin exerts the inhibitory response to inflammation by the inhibition of Nitric oxide production (note the abstract, page 107, col. 2, and discussion). What is lacking in Cuzzocrea is the teaching of the brain edema.

Guerrero teaches that melatonin inhibits the nitric oxide production after transient brain ischemia (note the abstract).

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The use of melatonin to prevent or treat brain edema would have been obvious to one of ordinary skill in the art since Cuzzocrea teaches the connection between the inhibition of nitric oxide by melatonin and the prevention and treatment of edema in experimental models and since Guerrero teaches the effectiveness of melatonin in inhibiting the nitric oxide production even in brain in ischemic conditions. In the absence of showing the criticality, the mode of administration of melatonin is deemed to be a parameter manipulatable by an artisan. One skilled in the art would be motivated to administer the composition orally in food composition as is evidenced by WO (note the abstract, and pages 22-24).

10. Claims 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cuzzocrea (J. Pineal Res., 24, pp 106-116, 1997) in view of Guerrero (J. Pineal Res. 24, 24-31, 1997), optionally further in view of Keller (5,891,465).

What is lacking in Cuzzocrea and Guerrero is the teaching of the administration of melatonin in liposomal form.

Keller teaches that administration of melatonin in liposomal form increases its bioavailability (note col. 3 and Example 1).

The administration of melatonin in a liposomal form would have been obvious to one of ordinary skill in the art because of its increased bioavailability as taught by Keller.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

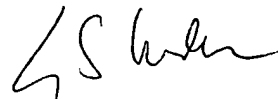
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

March 12, 2002